EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Barbara Schwalge on 3/18/08.

The application has been amended as follows:

Amend claim 29 as follows:

29. *(currently amended)* A process as claimed in claim 1, wherein the water-soluble polymers are selected from the group consisting of alginates, pectins, galactomannans, carrageenans, dextran, curdlan, pullulan, gellan, chitin, gelatin, xanthans, hemicelluloses, cellulose derivatives selected from the group consisting of methylcellulose, hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose and carboxymethylcellulose, starch derivatives selected from the group consisting of carboxymethylstarch and degraded starch, maltodextrins, polyacrylic acid, polymethacrylic acid, acrylic acid/methacrylic acid copolymers, polyvinyl alcohols, high molecular weight polyethylene glycols, polyoxyethylene/polyoxypropylene block copolymers and high molecular weight polyvinylpyrrolidones.

Amend claim31 as follows:

31. *(currently amended)* A process as claimed in claim 1, wherein the lipophilic additives [substances] are selected from the group consisting of fatty alcohols, fatty acids, glycerides, fatty acid esters, fatty alcohol esters and lipophilic polymers.

The listing of claims below replaces all earlier versions:

1. *(previously presented)* A process for producing an oral dosage form with sustained release of active ingredient, wherein the dosage form comprises

a) a formulated mixture of polyvinyl acetate and polyvinylpyrrolidone which acts as a binder and a matrix former, and wherein the polyvinylpyrrolidone has a molecular weight of from 20,000 to 1,000,000, and the polyvinylpyrrolidone is finely dispersed in the polyvinyl acetate,

b) at least one active ingredient,

c) optionally water-soluble polymers or low or high molecular weight lipophilic additives,

d) and, optionally, excipients,

wherein the process comprises ganulating a mixture of a) to d) or a) to c) or a) and b) and d) or a) and b) by heating to a temperature of from 40°C to 130°C in the absence of solvents.

2. (previously presented) A process as claimed in claim 1, wherein the polyvinyl acetate to polyvinylpyrrolidone ratio is 6:4 to 9:1.

3. (previously presented) A process as claimed in claim 1, wherein the active ingredient : water-soluble polymers or low or high molecular weight lipophilic additives ratio employed is from 5:95 to 85:15.

4. *(previously presented)* A process as claimed in claim 1, wherein polyvinyl acetate and polyvinylpyrrolidone each have a molecular weight of from 20,000 to 1,000,000.

5. *(previously presented)* A process as claimed in claim 1, wherein the mixture is granulated by heating to from 45 to 100°C.

6. *(previously presented)* A process as claimed in claim i, wherein the particle size of the active ingredients employed is in a range from 20 to 700 mm.

7. *(previously presented)* A process as claimed in claim 1, wherein the excipients employed are fillers, disintegrants and adsorbents, lubricants, flowability agents, dyes, stabilizers, antioxidants, wetting agents, preservatives, release agents, flavorings or sweeteners.

8. *(previously presented)* A process as claimed in claim 1, wherein fillers selected from the group consisting of lactose, cellulose powder, mannitol, calcium diphosphate and starch are employed as excipients.

9. *(previously presented)* A process as claimed in claim 1, wherein the granules can be produced by employing the process of mixer granulation, fluidized bed granulation or extrusion granulation.

10. - 11. *(canceled)*

12. *(previously presented)* A process as claimed in claim 1, wherein besides the formulated mixture of polyvinyl acetate and polyvinylpyrrolidone, further release-sustaining excipients may optionally be employed before, during or after the granulation.

13. *(previously presented)* A process as claimed in claim 1, wherein water-soluble, water-soluble highly swelling or lipophilic excipients are employed for further modification of release.

14. - 15. *(canceled)*

16. *(previously presented)* A process as claimed in claim 1, wherein the water-soluble polymers are selected from the group consisting of: polyvinyl alcohols, polyethylene glycols, polyoxyethylene/polyoxypropylene block copolymers, polyvinylpyrrolidones, vinyl acetate/vinyl pyrrolidone copolymers, polyethylene glycols, polyvinylpyrrolidones, vinyl acetate/vinylpyrrolidone copolymers, maltodextrins, and salts thereof.

17. - 26. *(canceled)*

27. *(previously presented)* A process as claimed in claim 1, wherein the production is either continuously or batchwise.

28. *(previously presented)* A process as claimed in claim 1, wherein the granulated mixture is further processed by forced screening of the granules in the hot state or in the cooled state.

29. *(currently amended)* A process as claimed in claim 1, wherein the water-soluble polymers are selected from the group consisting of alginates, pectins, galactomannans, carrageenans, dextran, curdlan, pullulan, gellan, chitin, gelatin, xanthans, hemicelluloses, cellulose derivatives selected from the group consisting of methylcellulose, hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose and carboxymethylcellulose, starch derivatives selected from the group consisting of carboxymethylstarch and degraded starch, maltodextrins, polyacrylic acid, polymethacrylic acid, acrylic acid/methacrylic acid copolymers, polyvinyl alcohols, high molecular weight polyethylene glycols, polyoxyethylene/polyoxypropylene block copolymers and high molecular weight polyvinylpyrrolidones.

30. *(Canceled)*

31. *(Currently amended)* A process as claimed in claim 1, wherein the lipophilic additives [substances] are selected from the group consisting of fatty alcohols, fatty acids, glycerides, fatty acid esters, fatty alcohol esters and lipophilic polymers.

32. *(previously presented)* A process as claimed in claim 31, wherein the fatty alcohol is stearyl alcohol; the fatty acid is stearic acid; and the lipophilic polymers are selected from the group consisting of ethylcellulose, cellulose acetate, acrylic ester/methacrylic ester copolymers, methacrylic *acid/acrylic* ester copolymers, cellulose acetate phthalate, cellulose acetate succinate, hydroxypropylmethylcellulose acetate phthalate and hydroxypropylmethyl-cellulose acetate succinate.

33. *(canceled)*

Reasons for allowance

2. The following is an examiner's statement of reasons for allowance: The primary reason for allowance of the claims is that Ortega does not granulate a combination of an active agent, polyvinylpyrrolidone and polyvinyl acetate in the absence of a solvent.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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